SMG 1410.21

FDA STAFF MANUAL GUIDES, VOLUME II - DELEGATIONS OF AUTHORITY

REGULATORY - GENERAL REDELEGATIONS OF AUTHORITY

GENERAL REDELEGATIONS OF AUTHORITY FROM THE COMMISSIONER TO OTHER OFFICERS OF THE FOOD AND DRUG ADMINISTRATION

Effective Date: July 5, 2012

1. AUTHORITY DELEGATED AND TO WHOM DELEGATED

A. Final authority of the Commissioner of Food and Drugs (Commissioner) is redelegated as referenced in the 1410 series of the Agency's Staff Manual Guides (SMGs). The Commissioner may continue to exercise all delegated authority referenced in these SMGs.

B. The following officials are authorized to perform all delegable functions of the Commissioner. These officials may not further redelegate this authority, or any part of this authority, except as elsewhere specified:

1. Counselor to the Commissioner, Office of the Counselor to the Commissioner (OCTC), Office of the Commissioner, (OC)

2. Deputy Commissioner for Medical Products and Tobacco, Office of Medical Products and Tobacco (OMPT)

3. Chief of Staff, OC

4. Chief Operating Officer, Office of Operations (OO)

5. Deputy Commissioner for Foods, Office of Foods (OF)

6. Deputy Commissioner for Global Regulatory Operations and Policy, Office of Global Regulatory Operations and Policy (OGROP)

7. Chief Scientist, Office of the Chief Scientist (OCS), OC

8. Associate Commissioner for Regulatory Affairs, Office of Regulatory Affairs (ORA), OGROP

C. The Federal Vacancies Reform Act of 1998 (Vacancies Reform Act) applies if the Commissioner dies, resigns, or is otherwise unable to perform the functions and duties of the Office of the Commissioner.

1. During an absence of the Commissioner that does not trigger the requirements of the Vacancies Reform Act, the first official in the following order who is available or the official in the following list who has been designated by the Commissioner to act shall lead the Agency (Specific delegations provided below do not limit the general delegations provided by this section to the designated officials who are authorized to perform all of the delegable functions of the Commissioner):

    a. Counselor to the Commissioner, OCTC, OC

    b. Deputy Commissioner for Medical Products and Tobacco, OMPT

    c. Chief of Staff, OC

    d. Chief Operating Officer, OO

    e. Deputy Commissioner for Foods, OF

    f. Deputy Commissioner for Global Regulatory Operations and Policy, OGROP

    g. Chief Scientist, OCS, OC

    h. Associate Commissioner for Regulatory Affairs, ORA, OGROP

    These officials may not further redelegate this authority, except as provided below.

2. When the Vacancies Reform Act applies, the Deputy Commissioner for Medical Products and Tobacco, OMPT shall act as Commissioner unless the Deputy Commissioner for Medical Products and Tobacco, OMPT does not meet the requirements of the Vacancies Reform Act or the President has directed someone else to act as Commissioner pursuant to the Vacancies Reform Act.

D. Authority delegated to a position by title may be exercised by a person officially designated to serve in that position in an acting capacity or on a temporary basis, unless prohibited by a restriction in the document designating him/her as "acting" or unless not legally permissible.

E. The following officials are authorized to perform all the functions of the officials under them in their respective offices and they may not further redelegate this authority:

    1. Counselor to the Commissioner, OCTC, OC

2. Deputy Commissioner for Medical Products and Tobacco, OMPT

3. Chief Operating Officer, OO

4. Chief Scientist, OCS, OC

5. Deputy Commissioner for Foods, OF

6. Deputy Commissioner for Global Regulatory Operations and Policy, OGROP

7. Associate Commissioner for Regulatory Affairs, ORA, OGROP

8. Chief Counsel, Office of the Chief Counsel

9. Associate Commissioner for Policy and Planning, Office of Policy and Planning (OPP), OC

F. The Deputy Commissioner for Medical Products and Tobacco, OMPT is authorized:

1. To make determinations that advisory committee meetings are concerned with matters listed in 5 U.S.C. 552(b) and therefore may be closed to the public in accordance with Title 21, Code of Federal Regulations (21 CFR) 14.27.

2. To perform other associated advisory committee functions, e.g., establishing technical and scientific review groups (advisory committees); appointing and paying members; approving waivers to appoint members to established advisory committees; renewing and rechartering of established advisory committees; amending charters of established advisory committees; and terminating established advisory committees.

3. To approve conflict of interest waivers for Special Government Employees (SGEs) and regular government employees serving on advisory committees in accordance with 21 U.S.C. 379d-1 and 18 U.S.C. 208(b)1 and 208(b)(3), as amended.

4. To select temporary members to advisory committees if such voting members are serving on an advisory committee managed by another Center.

5. To issue Federal Register (FR) Notices relating to advisory committee activities.

6. To further redelegate the authorities in paragraphs F.1-F.5 above to the Associate Commissioner for Special Medical Programs, Office of Special Medical Programs (OSMP), OMPT. In addition, in the event of absence or a vacancy in the position, the Associate Commissioner for Policy and Planning, OPP, OC, is designated to perform the functions in paragraphs F.1.-F.5 above.

7. Under Section 503(g)(4)(E)(ii) of the Federal, Food, Drug and Cosmetic Act (FFDCA), as added by Section 204 of the Medical Device User Fee Modernization Act of 2002 (MDUFMA), with respect to combination products the following: "During the review process, any dispute regarding the substance of premarket review may be presented to the Commissioner of Food and Drugs after first being considered by the Agency Center with primary jurisdiction of the premarket review, under the scientific dispute resolution procedures for such Center. The Commissioner of Food and Drugs shall consult with the Director of the Office [of Combination Products, OSMP, OMPT] in resolving the substantive dispute."

G. The Associate Commissioner for Policy and Planning, OPP, OC, and the Assistant Commissioner for Policy, Office of Policy (OP), OPP, OC, are authorized:

1. To perform any of the functions of the Commissioner with respect to the issuance of FR notices and proposed and final regulations of the Food and Drug Administration. This authority may not be further redelegated.

2. To issue responses to the following matters under part 10 of 21 CFR as follows and these officials may not further redelegate this authority:

   a. Requests for waiver, suspension, or modification of procedural requirements under Section 10.19 of 21 CFR

   b. Citizen petitions under Section 10.30 of 21 CFR

   c. Petitions for reconsideration under Section 10.33 of 21 CFR

   d. Petitions for stay under Section 10.35 of 21 CFR

   e. Requests for advisory opinions under Section 10.85 of 21 CFR

3. With respect to any matter delegated to the Associate Commissioner for Policy and Planning, OPP, OC, and the Assistant Commissioner for Policy, OP, OPP, OC, under this paragraph, the Associate

Commissioner for Policy and Planning, OPP, OC, and the Assistant Commissioner, OP, OPP, OC, are authorized to perform the functions of the Commissioner under Section 10.40, 10.45, 10.50, 10.55, 10.60, 10.65, 10.80, 10.90, and 10.95 of 21 CFR and of a Deputy Commissioner under Section 10.206(g) and (h) of 21 CFR. These authorities may not be further redelegated.

4. Under the Regulatory Flexibility Act (5 U.S.C. 605(b)) to certify that a proposed or final rule, if issued, will not have a significant economic impact on a substantial number of small entities. The Associate Commissioner for Policy and Planning, OPP, OC, and the Assistant Commissioner for Policy, OP, OPP, OC, may further redelegate this authority.

5. To make all determinations and findings under 21 CFR Part 15, and to waive, suspend, or modify any procedural requirements related to Part 15 under Section 10.19 of 21 CFR.

H. The Associate Director for Policy, Office of Regulatory Policy, Center for Drug Evaluation and Research (CDER), OMPT, is authorized:

1. To waive or reduce prescription drug user fees in situations where he or she finds that such a waiver or reduction: (1) is necessary to protect the public health under Section 736(d)(1)(A) of the FFDCA (21 U.S.C. 379h(d)(1)(A)), as amended; (2) is necessary because the fee would present a significant barrier to innovation under Section 736(d)(1)(B) of the FFDCA (21 U.S.C. 379h(d)(1)(a)), as amended; or (3) is appropriate under Section 736(d)(1)(D) of the FFDCA (21 U.S.C. 379h(d)(1)(D)), as amended because the applicant involved is a small business submitting its first human drug application. These authorities may not be further redelegated.

2. To act upon requests for consideration of any user fee decisions under Section 735 of the FFDCA (21 U.S.C. 379h), other than decisions on feeexceed-the cost waiver requests, made by such officers and the former Deputy User Fee Waiver Officer prior to July 1, 1999. These authorities may not be further redelegated.

I. The Director, Policy and Regulations Staff, Office of the Center Director, Center for Veterinary Medicine, Office of Foods is authorized:

1. To waive or reduce animal drug user fees in situations where he or she finds that such a waiver or reduction: (1) is necessary because the fee would present a significant barrier to innovation under Section 740(d)(1)(A) of the FFDCA (21 U.S.C. 379j-12(d)(1)(A)), as amended; (2) is necessary because the drug application or supplemental

application is intended solely for use of the animal drug in medicated feeds under Section 740(d)(1)(C) of the FFDCA (21 U.S.C. 379j-12(d)(1)(C)), as amended; (3) is necessary because the animal drug application or supplemental animal drug application is intended solely to provide for minor use or minor species indications under Section 740(d)(1)(D) of the FFDCA (21 U.S.C. 379j-12(d)(1)(D)), as amended; or (4) is appropriate under Section 740(d)(1)(E) of the FFDCA (21 U.S.C. 379h(d)(1)(E)), as amended because the applicant involved is a small business submitting its first animal drug application. This authority may not be redelegated.

2. To waive or reduce generic animal drug user fees in situations where he or she finds that such a waiver or reduction is necessary because the animal drug application or supplemental animal drug application is intended solely to provide for minor use or minor species indications under Section 741(d) of the FFDCA (21 U.S.C. 379j-21(d)), as amended.

3. Under any of the above cited provisions of Section 740 and 741 of the FFDCA, to act upon requests for reconsideration of decisions made. This authority may not be redelegated.

J. The Associate Director for Policy and Communications, Office of the Director, CVM, OF, is authorized to act upon requests for reconsideration of decisions made under any provision of Sections 740 and 741 of the FFDCA, except for those decisions that pertain to fee-exceed-the cost waiver requests. This authority may not be further redelegated.

K. The Chief Operating Officer, OO, is authorized to perform the functions of the Commissioner under:

1. Section 736(d)(1)(c) of the FFDCA (21 U.S.C. 379h (d)(1)(C)), as amended, to waive or reduce prescription drug user fees in situations where he or she finds that "the fees will exceed the anticipated present and future costs." The Chief Operating Officer, OO, may further redelegate the authority in this paragraph in whole or in part to the Associate Commissioner for Finance, Budget and Acquisitions, Office of Finance, Budget and Acquisitions (OFBA), OO.

2. Section 740(d)(1)(B) of the FFDCA, to waive or reduce animal drug user fees, for waiver or reduction request made on the basis that the fees assessed exceed the costs to FDA for reviewing applications. The Chief Operating Officer, OO, may further redelegate the authority in this paragraph in whole or in part to the Associate Commissioner for Finance, Budget and Acquisitions, OFBA, OO.

3. Section 736(c)(4) of the FFDCA, as amended by the Prescription Drug User Fee Act Amendments of 2002, to establish application, product, and establishment fees under Section 736(a), based on the revenue amounts established under Section 736(b) and the adjustments under 736(c). The Chief Operating Officer, OO, may further redelegate the authority in this paragraph in whole or in part to the Associate Commissioner for Finance, Budget and Acquisitions, OFBA, OO.

4. Section 738 of the FFDCA, as added by the MDUFMA, to adjust and set fee rates for medical device applications each year. The Chief Operating Officer, OO, may further redelegate the authority in this paragraph in whole or in part to the Associate Commissioner for Finance, Budget and Acquisitions, OFBA, OO.

5. Section 740(c)(4) of the FFDCA, to adjust and set new and supplemental animal drug application fees, animal drug sponsor fees, animal drug product fees, and animal drug establishment fees. The Chief Operating Officer, OO, may further redelegate the authority in this paragraph in whole or in part to the Associate Commissioner for Finance, Budget and Acquisitions, OFBA, OO.

6. Section 741(c)(3) of the FFDCA, to adjust and set abbreviated application fees, generic new animal drug sponsor fees, and generic new animal drug product fees. The Chief Operating Officer, OO, may further redelegate the authority in this paragraph in whole or in part to the Associate Commissioner for Finance, Budget and Acquisitions, OFBA, OO.

7. Section 919(b)(6)) of the FFDCA (21 U.S.C. 387s(c)(6)), to notify each manufacturer and importer of tobacco products subject to this Section of the amount of the quarterly assessment due for such products. The Chief Operating Officer, OO, may further redelegate the authority in this paragraph in whole or in part to the Associate Commissioner for Finance, Budget and Acquisitions, OFBA, OO.

8. Under any fees-exceed-cost user fee waiver or reduction sections of the FFDCA noted above, act upon requests for reconsideration of decisions made by such officers. This authority may not be redelegated.

L. The Chief Scientist, OCS, OC, is designated as the User Fee Appeals Officer. The User Fee Appeals Officer is authorized to hear and decide user fee waiver appeals. The decision of the User Fee Appeals Officer will constitute final agency action on such matters. The User Fee Appeals Officer may not further redelegate this authority.

M. The Chief Operating Officer, OO, is authorized to perform all of the administrative authorities (i.e., financial, personnel, facilities management, property management, etc.) of the Commissioner. These authorities may be further redelegated, except when specifically prohibited.

N. The following officials are authorized to deny a request to issue an emergency use authorization (EUA) under Section 564 of the FFDCA, and to consult under Section 564(c) of the FFDCA, requiring "consultation with the Director of the National Institutes of Health and the Director of the Centers for Disease Control and Prevention (to the extent feasible and appropriate given the circumstances of the emergency involved)" prior to issuing an EUA:

1. Chief Scientist, OCS, OC

2. Deputy Commissioner for Medical Products and Tobacco, OMPT

3. Director, Center for Biologics Evaluation and Research (CBER), OMPT

4. Director, CDER, OMPT

5. Director, Center for Devices and Radiological Health (CDRH), OMPT

O. The following officials are authorized to issue the final decision regarding the disqualification of a clinical investigator, i.e., the investigator's eligibility to receive investigational articles under 21 CFR 312.70(b), 511.1(c)(2), or 812.119(b):

1. Deputy Commissioner for Medical Products and Tobacco, OMPT

2. Chief Scientist, OCS, OC

3. Associate Commissioner for Special Medical Programs, OMPT

P. The following officials are authorized to sign a consent agreement between the FDA and a clinical investigator regarding the disqualification of the clinical investigator, resulting in the clinical investigator's ineligibility to receive investigational articles under 21 CFR 312.70(b), 511.1(c)(2), or 812.119(b) and containing a binding provision that disqualification pursuant to the consent agreement has the same legal effect as being disqualified pursuant to the relevant regulation after a Part 16 Hearing. These officials may not further redelegate this authority.

1. Director, CBER, OMPT

2. Director and Deputy Director, Office of Compliance and Biologics Quality (OCBQ), CBER, OMPT

3. Director, CDER, OMPT

4. Director and Deputy Director, Office of Compliance, CDER, OMPT

5. Director and Deputy Director, Division of Scientific Investigations (DSI), Office of Compliance, CDER, OMPT

6. Director, CVM, OF

7. Director and Deputy Director, Office of Surveillance and Compliance (OSC), CVM, OF

8. Director, Division of Compliance, OSC, CVM, OF

9. Director, CDRH, OMPT

10. Deputy Director for Science, CDRH, OMPT

11. Director, Office of Compliance, CDRH, OMPT

12. Deputy Director for Medical Affairs, Office of Compliance, CDRH, OMPT

2. REDELEGATION

Except as otherwise provided, these Officials may not further redelegate these authorities.

3. EFFECTIVE DATE

The Commissioner of Food and Drugs approved this delegation on July 5, 2012.

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	12/07/2009	N/a	OC/OA/ OM/OMP	Margaret A. Hamburg, M.D. Commissioner of Food and Drugs
Revision	06/08/2010	N/a	OC/OA/ OM/OMP	Margaret A. Hamburg, M.D. Commissioner of Food and Drugs
Revision	10/11/2011	N/a	OO/OM	Margaret A. Hamburg, M.D. Commissioner of Food and Drugs
Revision	07/05/2012	N/a	OO/OBS	Commissioner of Food and Drugs